



# UNITED STATES PATENT AND TRADEMARK OFFICE

*BT*  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

| APPLICATION NO.        | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|-------------|-------------------------|---------------------|------------------|
| 10/069,386             | 09/12/2002  | Moulay A. Alaoui-Jamali | SWA-001US)          | 3268             |
| 32254                  | 7590        | 07/22/2005              | EXAMINER            |                  |
| KEOWN & ASSOCIATES     |             |                         | WHITEMAN, BRIAN A   |                  |
| 500 WEST CUMMINGS PARK |             |                         |                     |                  |
| SUITE 1200             |             |                         | ART UNIT            | PAPER NUMBER     |
| WOBURN, MA 01801       |             |                         | 1635                |                  |

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

|                            |                      |  |
|----------------------------|----------------------|--|
| Application No.            | ALAOUI-JAMALI ET AL. |  |
| Examiner<br>Brian Whiteman | Art Unit<br>1635     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 4/13/05.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 1-4, 6, 10 and 11 is/are pending in the application.  
 4a) Of the above claim(s) 11 is/are withdrawn from consideration.  
 5) Claim(s) 1, 3, 10 is/are allowed.  
 6) Claim(s) 2, 4 and 6 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

**Final Rejection**

Claims 1-4, 6, 10-11 are pending.

Applicant's traversal, the amendment to the specification, the amendment to claims 1-4 and 6, the cancellation of claims 5 and 7-9, and the addition of new claims 10-11 in paper filed on 4/13/05 is acknowledged and considered by the examiner.

***Election/Restrictions***

New claim 11 is directed to a non-elected invention (inhibiting the expression of a gene encoding the polypeptide having the amino acid set forth in SEQ ID NO: 2) and is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/20/04.

***Specification***

The amendment filed 4/13/05 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows: 1) amendment to the origin SEQ ID NO: 1 in the paper of copy. The origin was unknown and the applicants have amended the origin as human.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation ‘isolated or recombinant nucleotide sequence being from a human species’ in claims 2 and 4 is not supported by the as-filed specification. There appears to be no written description of the limitation in the application as filed. See MPEP § 2163.06. Applicants cite Figure 1 and page 4, lines 26-27 and a journal article (C9, Cho et al.) published after the filing date for support of the limitation. Figure 1 and page 4 do not disclose that SEQ ID NO: 1 is a nucleotide sequence from a human species. Page 4, lines 26-27 recites that the gene may be from a human, mouse, rat and yeast. Therefore, there is nothing in the instant specification that would lead the skilled artisan to conclude that the limitation was supported by the specification as filed.

“It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose.” *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

It is apparent that the applicants at the time the invention was made did not intend or contemplate the limitation in amended claims 2 and 4 as part of the disclosure of their invention. There is no evidence in the specification that the applicants were in possession of the claimed nucleotide sequence as set forth in the claims 2 and 4, as it is now claimed, at the time the application was filed.

Applicant's arguments with respect to claims 2 and 4 have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 6 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 remains rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: method steps to complete the pre-amble of the claim. The claim does not recite where the nucleotide is expressed. Is the nucleotide sequence expressed in a cell in vitro, a cell in vivo, a transgenic animal, or an animal?

Applicant's arguments filed 4/13/05 have been fully considered but they are not persuasive because the claim is still missing steps to complete the preamble of the claim.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how expression of the isolated nucleotide sequence according to claim 1 is related to increasing the transcription of a gene. Is the gene operably linked to the nucleotide sequence?

***Response to Arguments***

Applicant's arguments, see page 5, filed 4/13/05, with respect to 101 rejection have been fully considered and are persuasive. The rejection of claims 1-4 has been withdrawn.

Applicant's arguments, see pages 5-7, filed 4/13/05, with respect to 112 rejection have been fully considered and are persuasive. The rejection of claim 6 has been withdrawn.

***Conclusion***

Claims 1, 3, and 10 are free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman  
Patent Examiner, Group 1635

*Brian Whiteman*  
AU1632